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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,361	03/16/2001	Catherine Guenther	R-125	7726

7590 04/09/2003

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EXAMINER	
QIAN, CELINE X	

ART UNIT	PAPER NUMBER
1636	18

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/811,361	GUENTHER, CATHERINE	
	Examiner	Art Unit	
	Celine X Qian	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *23 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49 and 51-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *49* is/are allowed.

6)☒ Claim(s) *51,52 and 54-56* is/are rejected.

7)☒ Claim(s) *53* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 49, 51-56 are pending in the application. Claims 11-16, 25-48 and 50 are cancelled.

This Office Action is in response to the Amendment filed on 1/23/03.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/23/03 has been entered.

Response to Amendment

The rejection of claims 42-48 under 35 U.S.C.112 first paragraph is moot in light of Applicants' cancellation of the claims.

The rejection of claims 38-41 and 50 under 35 U.S.C.103 (a) is moot in light of Applicants' cancellation of the claims.

Claims 51, 52 and 54-56 are rejected under 35 U.S.C.112 first paragraph (scope of enablement) for reasons set forth of the record mailed on 10/23/02 and further discussed below.

Claims 54-56 are rejected under 35 U.S.C.112 second paragraph for reasons discussed below.

Claim 53 is objected to for reasons discussed below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 51, 52, 54-56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic mouse comprising a homozygous disruption of the retina-specific nuclear receptor gene that lacks production of functional retina-specific nuclear receptor protein, wherein said mouse exhibits the phenotype of eye abnormality, a method of making said mouse by introducing the knockout construct into embryonic stem (ES) cells, selecting ES cells comprising retina-specific nuclear receptor knockout construct, introducing said ES cells into blastocyst, producing a chimeric mouse, mating the chimeric mouse to get a heterozygous transgenic mouse, and further mating the heterozygous transgenic mouse to obtain a homozygous knockout mouse, does not reasonably provide enablement for a heterozygous transgenic mouse comprising a disruption of the retina-specific nuclear receptor gene, said mouse that lacks functional retina-specific nuclear receptor protein and exhibits an eye abnormality, and a method of making said knockout mouse by introducing the claimed method without further mating the heterozygous transgenic mouse. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The newly added claims 51, 52, 54-56 are rejected for same reasons as applied to now cancelled claims 42-48 that set forth of the record mailed on 10/23/03 (see pages 3-5).

The nature of the invention is a transgenic mouse comprising a disruption in a retina-specific nuclear receptor gene and exhibits phenotype comprising retinal dysplasia; and a method of making said transgenic mouse.

The specification discloses that only the homozygous knockout mice exhibit the phenotype comprising retinal dysplasia (see page 59-60, lines 30-36 and line 5-9). The specification discloses a method for generating said mouse by homologous recombination using a retina-specific nuclear receptor-targeting construct (see page 54-60, examples 1-4). Said method comprises the steps of introducing the knockout construct into embryonic stem (ES) cells, selecting ES cells comprising retina-specific nuclear receptor knockout construct, introducing said ES cells into blastocyst, producing a chimeric mouse, mating the chimeric mouse to get a heterozygous transgenic mouse, and further mating the heterozygous transgenic mouse to obtain a homozygous knockout mouse that lacks production of functional retina-specific protein and exhibits an eye abnormality.

Claims 51, 52, 54-56 encompass heterozygous mouse. The heterozygous mouse comprises one allele having a normal retina-specific nuclear receptor gene; hence it expresses functional retina-specific nuclear receptor protein. Therefore, the heterozygous mouse would not be expected to have the phenotype of retinal dysplasia as the homozygous mouse. In addition, the method of making homozygous mouse would require the step of mating the heterozygous mouse and select the offspring that comprises homozygous disruption of the retina-specific nuclear receptor gene. The specification does not teach how to use a transgenic mouse without the disclosed phenotype, and a method to make homozygous mouse without the step of breeding the heterozygous mouse. Therefore, one skilled of art would have to engage in undue experimentation to determine how to use mice that do not have the disclosed phenotype, and how to make a homozygous transgenic mouse without the step of breeding the heterozygous mice.

This rejection can be overcome by limiting the claims to a homozygous mouse and reciting the breeding of heterozygous mouse to obtain the homozygous mouse.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 55 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 55 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: breeding the heterozygous transgenic mouse to obtained the homozygous transgenic mouse that lacks production of functional retina specific nuclear receptor protein and exhibits an eye abnormality.

Claim Objections

Claim 53 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 49 is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.
April 4, 2003

Anne-Marie Falk
ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER